

Eton Pharmaceuticals Announces FDA Acceptance of New Drug Application for ET-105

-ET-105 assigned Prescription Drug User Fee Act (PDUFA) target action date of March 17, 2020

DEER PARK, Ill., Aug. 01, 2019 (GLOBE NEWSWIRE) -- Eton Pharmaceuticals, Inc (Nasdaq: ETON), a specialty pharmaceutical company focused on developing and commercializing innovative drug products, today announced that Aucta Pharmaceuticals' New Drug Application for ET-105, an innovative formulation of lamotrigine which Eton acquired the U.S. marketing rights to in June 2019, has been accepted for review by the U.S. Food and Drug Administration (FDA). The FDA has assigned the application a Prescription Drug User Fee Act (PDUFA) target action date of March 17, 2020.

"The NDA acceptance of ET-105 marks an important milestone for Eton as this strengthens our growing pipeline of near-launch products. We are very excited about the potential for ET-105 to address a significant unmet need in this large and growing market," said Sean Brynjelsen, Chief Executive Officer of Eton Pharmaceuticals. "Our team looks forward to working with Aucta and the FDA over the coming months as we prepare for a potential commercial launch in the first half of 2020."

ET-105 is a patent-pending formulation of lamotrigine, for which Aucta is seeking approval as an adjunct therapy for partial seizures, primary generalized tonic-clonic seizures, and generalized seizures of Lennox-Gastaut syndrome in patients two years of age and older. Lamotrigine is one of the most widely used anti-epilepsy medications in the U.S. with sales exceeding \$700 million and 1 billion tablets annually but is only FDA-approved in tablet formulations. ET-105's innovative formula will be delivered to patients as an oral liquid and has been developed specifically to address the significant unmet need in patients with dysphagia and pediatric patients requiring precision dosing at levels below the currently available tablet strengths.

About Eton Pharmaceuticals

Eton Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on developing and commercializing innovative products utilizing the FDA's 505(b)(2) regulatory pathway. Eton is primarily focused on liquid dosage forms including injectables, oral liquids and ophthalmics. Eton has a diversified pipeline of high-value product candidates in various stages of development and therapeutic areas, including multiple product candidates currently pending regulatory approval with the FDA.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements associated with the expected ability of Eton and its partner to undertake certain activities and accomplish certain goals and objectives. These statements include but are not limited to statements regarding the expected impact of the FDA's Complete Response Letter, the timing of a response to such letter, the ability to resolve the issues raised by the letter and the timing of such resolution, the approvability of the product in light of this letter and the timing of such approval and launch. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Eton's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks associated with the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs. These and other risks concerning Eton's business, development programs, and financial condition are described in additional detail in Eton's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Eton undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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Source: Eton Pharmaceuticals



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